

P28460.IDS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Kazutoshi WATANABE et al.

Group Art Unit: 1624

Appln. No. : 10/550,299  
(National Stage of PCT/JP2004/004320)

Examiner: BALASUBRAMANIAN

I.A. Filed : March 26, 2004

Confirmation No.: 1935

For : 2,3,6-TRISUBSTITUTED-4-PYRIMIDONE DERIVATIVES

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop Amendment  
Randolph Building  
401 Dulany Street  
Alexandria VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicants hereby bring the following information to the attention of the Examiner, which includes information cited and discussed in the specification, the International Search Report, and the International Preliminary Report on Patentability issued in connection with International Application No. PCT/JP2004/004320. Copies of the International Search Report (in English), and the International Preliminary Examination Report (in English) were enclosed with the papers when entering the National Stage on September 21, 2005. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein.

G. GLENNER et al., Biochemical and Biophysical Research Communications, Vol. 120, No. 3, 1984, pp. 885-890, which is cited on page 1 of the specification;

03/15/2007 MAHMEI 00000134 10550299

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C.L. MASTERS et al., The EMBO Journal, Vol. 4, No. 11, 1985, pp. 2757-2763, which is cited on page 1 of the specification;

C.L. MASTERS et al., Proc. Natl. Acad. Sci. USA, Vol. 82, June 1985, pp. 4245-4249, which is cited on page 1 of the specification;

C.M. WISCHIK et al., Proc. Natl. Acad. Sci. USA, Vol. 85, June 1988, pp. 4506-4510, which is cited on page 2 of the specification;

J. KONDO et al., Neuron, Vol. 1, November 1988, pp. 827-834, which is cited on page 2 of the specification;

R. SHERRINGTON et al., Nature, Vol., 375, June 29, 1995, pp. 754-760, which is cited on page 2 of the specification;

E. LEVY-LAHAD et al., Science, Vol. 269, August 18, 1995, pp. 973-977, which is cited on page 2 of the specification;

E.I. ROGAEV et al., Nature, Vol. 376, August 31, 1995, pp. 775-778, which is cited on page 2 of the specification;

D.R. BORCHELT et al., Neuron, Vol. 17, November 1996, pp. 1005-1013, which is cited on page 2 of the specification;

T. TOMITA et al., Proc. Natl. Acad. Sci. USA, Vol. 94, March 1997, pp. 2025-2030, which is cited on page 2 of the specification;

Sai-Shin Igaku, Vol. 49, No. 9, 1994, pp. 1506-1512, which is cited on page 2 of the specification;

D.W. DICKSON et al., Society for Neuroscience Abstracts, Vol. 17, 1991, pp. 1445, which is cited on page 2 of the specification;

R. SIMAN et al., The Journal of Neuroscience, Vol. 10, No. 7, July 1990, pp. 2400-2411, which is cited on page 2 of the specification;

Shin-kei Shinpo, Vol. 34, 1990, pp. 343-349, which is cited on page 2 of the specification;

Tanpaku-shitu Kaku-san Koso, Vol. 41, 1996, pp. 1476-1483, which is cited on pages 2 and 3 of the specification;

Tanpaku-shitu Kaku-san Koso, Vol. 36, 1991, pp. 2-11, which is cited on page 3 of the specification;

Igaku no Ayumi, Vol. 158, No. 9, August 31, 1991, pp. 511-514, which is cited on page 3 of the specification;

Y. IHARA et al., J. Biochem., Vol. 99, 1986, pp. 1807-1810, which is cited on page 3 of the specification;

I. GRUNDKE-IQBAL et al., Proc. Natl. Acad. Sci. USA, Vol. 83, July 1986, pp. 4913-4917, which is cited on page 3 of the specification;

Seikagaku, Vol. 64, No. 5, pp. 308-312, which is cited on page 3 of the specification;

K. ISHIGURO et al., J. Biol. Chem., Vol. 267, No. 15, May 25, 1992, pp. 10897-10901, which is cited on page 4 of the specification;

JP HEI 6-239893, together with an English language abstract, which is cited on page 3 of the specification;

K. ISHIGURO et al., FEBS Lett., Vol. 325, July 1993, pp. 167-172, which is cited on page 3 of the specification;

B.A. YANKNER et al., Science, Vol. 250, 1990, pp. 279-283, which is cited on page 3 of the specification;

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A. TAKASHIMA et al., Proc. Natl. Acad. Sci. USA, Vol. 90, August 1993, pp. 7789-7793, which is cited on page 4 of the specification;

JP HEI 6-329551, together with an English language abstract, which is cited on page 4 of the specification;

WO 98/24782, which is cited on page 5 of the specification;

EP 0 354 179 A, which is cited on page 254 of the specification;

JP 52-139085, which is cited on page 255 of the specification, and family member U.S. Patent No. 4,166,180;

EP 1 136 482, and family member U.S. Patent Application Publication No. 2003/0187004 A1;

WO 03/027080; and

WO 03/027088.

Applicants also bring to the attention of the Examiner:

U.S. Patent No. 6,586,441;

U.S. Patent No. 4,507,302;

U.S. Patent No. 4,619,933;

EP 0 168 262, accompanied by U.S. family member U.S. Patent No. 4,725,600;

JP SHO 49-035631

JP SHO 49-35632;

JP SHO 49-035633

JP SHO 49-35634;

JP SHO 52-071481, accompanied by an English language abstract;

WO 98/24780

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WO 98/24782, accompanied by HU P001698 A and family members U.S. Patent Nos. 6,096,753, 6,410,729 B1, and 6,420,385 B1.

WO 93/11231;

Chemical Abstracts, Vol. 100, No. 28, 1984, Columbus, Ohio, US, Abstract No. 174768e, M.F. BRANA et al., "Reaction of N-(1-Oxido-4-Pyridylmethyl)-3,5-Dimethylbenzamide with Malononitrile in Acetic Anhydride", page 627; XP002127059;

Chemical Abstracts, Vol. 84, No. 7, 1976, Columbus, Ohio, US, Abstract No. 44112b, Tani et al., "4-Hydroxy-Pyridylpyrimidine Derivatives", Page 502, XP002127060;

Chemical Abstracts, Vol. 82, No. 28, 1975, Columbus, Ohio, US, Abstract No. 171028n, Tani et al., "2,4,5-Trisubstituted-6-Pyridylpyrimidine Derivatives", page 555, XP002127061;

Chemical Abstracts, Vol. 83, No. 28, 1975, Columbus, Ohio, US, Abstract No. 10127z, Tani et al., "5-Nitro-6-Pyridylpyrimidine Derivatives", page 853, XP002127062;

Chemical Abstract 1992, Vol. 116, Abstract # 59167;

Chemical Abstract 1966, Vol. 65, Abstract # 90645.

Von Hans-Joachim KABBE, "Substituierte 4-Hydroxy- und 4-Amino-Pyrimidine", Liebigs. Ann. Chem., Vol. 701, pp. 144-149 (1967); and

Harvey I. SKULNICK et al., "Pyrimidinones. 1. 2-Amino-5-Halo-6-Arly-4(3H)-Pyrimidinones. Interferon-Inducing Antiviral Agents", J. Med. Chem., Vol. 28, pp 1864-1869 (1985).

H. YINGLIN, Tetrahedron Letters, Vol. 30, No. 39, 1989, pp. 5285-5286.

H. YINGLIN, Synthesis, pp. 122-124, February 1990.

R.L. DUNCAN Jr. et al., J. Med. Chem., Vol. 13, No. 1, January 1970, pp. 1-6.

D.L. THAI et al., J. Med. Chem., Vol. 41, 1998, pp. 591-601.

P28460.IDS

HU 218974 B, and English language family member U.S. Patent No. 5,612,286

U.S. Patent No. 6,107,301

WO 01/70728 A1;

WO 01/70729 A1, and family member U.S. Patent No. 6,844,335;

Applicants also bring to the Examiner's attention the following applications, which disclose subject matter related to that of the present application:

U.S. Patent Application No. 09/787,426, to WATANABE et al., which is the national stage of PCT/JP99/05224, filed September 24, 1999, which published as WO 00/18758, on April 6, 2000;

U.S. Patent Application No. 10/489,606, to Uehara et al., which published as U.S. 2005/0090490 A1, which is the national stage of PCT/JP2002/09685, filed September 20, 2002, which published as WO 03/037888 on May 8, 2003;

U.S. Patent Application No. 10/489,607, to Uehara et al., which published as U.S. 2005/0130967 A1, which is the national stage of PCT/JP02/09684, filed September 20, 2002, which published as WO 03/027080, on April 3, 2003; and

U.S. Patent Application 10/538,766, to USUI et al. which is the national stage of PCT/JP2003/015968, filed December 12, 2003, which published as WO 2004/055007 A1, on July 1, 2004.

Applicants also bring to the attention of the Examiner documents cited by the Examiner in Office Actions mailed in the above cited U.S. Patent Application No. 09/787,426:

U.S. Patent No. 6,107,301;

U.S. Patent No. 6,844,335;

U.S. Patent Application Publication No. 2005/0130998 A1;

TANI et al., CAPLUS Abstract 84:44112 (1976);

Joachim ULRICH, Chapter 4: Crystallization, Krik-Othmer Encyclopedia of Chemical Technology (August 2002)

Anthony R. WEST, Solid State Chemistry and Its Applications", Wiley, New York, 1988 pp. 358 and 365; and

Sudha R. VIPPAGUNTA et al., "Crystalline Solids", Advance Drug Delivery Reviews, Vol. 48, pp. 3-26 (2001).

The Examiner is invited to review the related applications.

In accordance with 37 C.F.R 1.98 and the waiver thereof, copies of the U.S. Patents, U.S. Patent Application Publications, and U.S. Patent Applications, are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

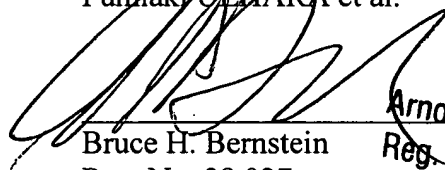
Copies of the above-noted documents, except for U.S. Patents, U.S. Patent Application Publications, and U.S. Patent Application, are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

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Applicants note that this disclosure statement is being filed after first action on the merits, but prior to issuance of an office action closing prosecution. Therefore, a check including the amount of \$180.00 is enclosed. However, if the fee is deficient and/or if any additional fee is required for consideration of this disclosure statement, including any fee under 37 C.F.R. 1.17(p), Applicants hereby authorize that any required fee be charged to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,  
Fumiaki UEHARA et al.

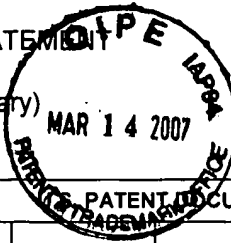


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FORM PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. P28460	Application No. 10/550,299
<b>INFORMATION DISCLOSURE STATEMENT</b> <b>BY APPLICANT</b> (Use several sheets if necessary)		Applicant Kazutoshi WATANABE et al.	
		I.A. Filing Date March 26, 2004	Group 1624



PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	6	- 2 3 9 8 9 3	08/30/94	JAPAN			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	G. GLENNER et al., Biochemical and Biophysical Research Communications, Vol. 120, No. 3, 1984, pp. 885-890,
	2	C.L. MASTERS et al., The EMBO Journal, Vol. 4, No. 11, 1985, pp. 2757-2763,
	3	C.L. MASTERS et al., Proc. Natl. Acad. Sci. USA, Vol. 82, June 1985, pp. 4245-4249.
	4	C.M. WISCHIK et al., Proc. Natl. Acad. Sci. USA, Vol. 85, June 1988, pp. 4506-4510.
	5	J. KONDO et al., Neuron, Vol. 1, November 1988, pp. 827-834.
	6	R. SHERRINGTON et al., Nature, Vol. 375, June 29, 1995, pp. 754-760.
	7	E. LEVY-LAHAD et al., Science, Vol. 269, August 18, 1995, pp. 973-977.
	8	E.I. ROGAEV et al., Nature, Vol. 376, August 31, 1995, pp. 775-778.
	9	D.R. BORCHELT et al., Neuron, Vol. 17, November 1996, pp. 1005-1013.
	10	T. TOMITA et al., Proc. Natl. Acad. Sci. USA, Vol. 94, March 1997, pp. 2025-2030.
	11	Sai-Shin Igaku, Vol. 49, No. 9, 1994, pp. 1506-1512.
	12	D.W. DICKSON et al., Society for Neuroscience Abstracts, Vol. 17, 1991, pp. 1445.
	13	R. SIMAN et al., The Journal of Neuroscience, Vol. 10, No. 7, July 1990, pp. 2400-2411.
	14	Shin-kei Shinpo, Vol. 34, 1990, pp. 343-349.
	15	Tanpaku-shitu Kaku-san Koso, Vol. 41, 1996, pp. 1476-1483.
	16	Tanpaku-shitu Kaku-san Koso, Vol. 36, 1991, pp. 2-11.
	17	Igaku no Ayumi, Vol. 158, No. 9, August 31, 1991, pp. 511-514.
	18	Y. IHARA et al., J. Biochem., Vol. 99, 1986, pp. 1807-1810.
	19	I. GRUNDKE-IQBAL et al., Proc. Natl. Acad. Sci. USA, Vol. 83, July 1986, pp. 4913-4917.
	20	Seikagaku, Vol. 64, No. 5, pp. 308-312.
	21	K. ISHIGURO et al., J. Biol. Chem., Vol. 267, No. 15, May 25, 1992, pp. 10897-10901.
	22	K. ISHIGURO et al., FEBS Lett., Vol. 325, July 1993, pp. 167-172.
	23	English Language Abstract of JP 6-239893, Date Publication 08/30/94.
	24	B.A. YANKNER et al., Science, Vol. 250, 1990, pp. 279-283.
	25	A. TAKASHIMA et al., Proc. Natl. Acad. Sci. USA, Vol. 90, August 1993, pp. 7789-7793.

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P28460Application No.  
10/550,299INFORMATION DISCLOSURE STATEMENT  
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Applicant  
Kazutoshi WATANABE et al.I.A. Filing Date  
March 26, 2004Group  
1624

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLA SS	SUBCLASS	FILING DATE IF APPROPRIATE
		6 5 8 6 4 4 1	07/01/03	BORRONI et al.			
	2003	0 1 8 7 0 0 4	10/02/03	ALMARIO GARCIO et al.			
		4 5 0 7 3 0 2	03/26/85	FAST et al.			
		4 6 1 9 9 3 3	10/28/86	STRINGFELLOW et al			
		4 7 2 5 6 0 0	02/16/88	TAKAYA et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
	6	- 3 2 9 5 5 1	11/29/94	JAPAN				
	98	/ 2 4 7 8 2	06/11/98	W.I.P.O				
	00	/ 1 8 7 5 8	04/06/00	W.I.P.O				
		0 1 6 8 2 6 2	01/15/86	E.P.O				
		1 1 3 6 4 8 2	09/26/01	E.P.O				
	49	- 0 3 5 6 3 1	04/02/74	JAPAN				
	49	- 3 5 6 3 2	04/02/74	JAPAN				
	49	- 0 3 5 6 3 3	04/02/74	JAPAN				
	49	- 3 5 6 3 4	04/02/74	JAPAN				
	52	- 0 7 1 4 8 1	06/14/77	JAPAN				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	26	H. YINGLIN, Tetrahedron Letters, Vol. 30, No. 39, 1989, pp. 5285-5286.
	27	English language Abstract of JP 6-329551 Date Publication 11/29/94.
	28	H. YINGLIN, Synthesis, pp. 122-124, February 1990.
	29	R.L. DUNCAN Jr. et al., J. Med. Chem., Vol. 13, No. 1, January 1970, pp. 1-6.
	30	D.L. THAI et al., J. Med. Chem., Vol. 41, 1998, pp. 591-601.
	31	Chemical Abstracts, Vol. 100, No. 28, 1984, Columbus, Ohio, US, Abstract No. 174768e, M.F. BRANA et al., "Reaction of N-(1-Oxido-4-Pyridylmethyl)-3,5-Dimethylbenzamide with Malononitrile in Acetic Anhydride", page 627; XP002127059.
	32	Chemical Abstracts, Vol. 84, No. 7, 1976, Columbus, Ohio, US, Abstract No. 44112b, Tani et al., "4-Hydroxy-Pyridylpyrimidine Derivatives", Page 502, XP002127060.
	33	Chemical Abstracts, Vol. 82, No. 28, 1975, Columbus, Ohio, US, Abstract No. 171028n, Tani et al., "2,4,5-Trisubstituted-6-Pyridylpyrimidine Derivatives", page 555, XP002127061.

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U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
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Kazutoshi WATANABE et al.I.A. Filing Date  
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6 0 9 6 7 5 3	08/01/00	SPOHR et al.			
		6 4 1 0 7 2 9	06/25/02	SPOHR et al.			
		6 4 2 0 3 8 5	07/16/02	SPOHR et al.			
	2005	0 0 9 0 4 9 0	04/28/05	UEHARA et al.			
		5 6 1 2 2 8 6	03/18/97	MAYER et al.			
		6 1 0 7 3 0 1	08/22/00	ALDRICH et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
	98	/ 2 4 7 8 0	06/11/98	W.I.P.O				
	98	/ 2 4 7 8 2	06/11/98	W.I.P.O				
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	03	/ 0 3 7 8 8 8	05/08/03	W.I.P.O				
		2 1 8 9 7 4	08/28/95	HUNGARY				
	P	0 0 0 1 6 9 8	04/28/01	HUNGARY				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	34	Chemical Abstracts, Vol. 83, No. 28, 1975, Columbus, Ohio, US, Abstract No. 10127z, Tani et al., "5-Nitro-6-Pyridylpyrimidine Derivatives", page 853, XP002127062.
	35	Chemical Abstract 1992, Vol. 116, Abstract # 59167.
	36	Chemical Abstract 1966, Vol. 65, Abstract # 90645.
	37	Von Hans-Joachim KABBE, "Substituierte 4-Hydroxy- und 4-Amino-Pyrimidine", Liebigs. Ann. Chem., Vol. 701, pp. 144-149 (1967).
	38	Harvey I. SKULNICK et al., "Pyrimidinones. 1. 2-Amino-5-Halo-6-Aryl-4(3H)-Pyrimidinones. Interferon-Inducing Antiviral Agents", J. Med. Chem., Vol. 28, pp 1864-1869 (1985).
	39	U.S. Patent Application 09/787,426, filed July 2, 2001 to WATANABE et al.
	40	English language Abstract of JP 52-071481, published 06/14/77.

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		6 1 0 7 3 0 1	08/22/00	ALDRICH et al.			
		6 8 4 4 3 3 5	01/18/05	ALMARIO GARCIA et al.			
	2005	/ 1 3 0 9 9 8	06/16/05	ALMARIO GARCIA et al.			
	2005	/ 1 3 0 9 6 7	06/16/05	UEHARA et al.			
		4 1 6 6 1 8 0	08/28/79	KATO et al.			

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		0 3 5 4 1 7 9	07/20/89	EPO			
	01	/ 0 7 0 7 2 8	09/27/01	WIPO			
	01	/ 0 7 0 7 2 9	09/27/01	WIPO			
	2004	/ 0 5 5 0 0 7	07/01/04	WIPO			
	03	/ 0 2 7 0 8 0	09/20/02	WIPO			
	52	- 1 3 9 0 8 5	11/19/77	JAPAN			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		U.S. Patent Application 10/538,766, filed December 12, 2003 to USUI et al.
		TANI et al., CAPLUS Abstract 84:44112 (1976)
		Joachim ULRICH, Chapter 4: Crystallization, Krik-Othmer Encyclopedia of Chemical Technology (August 2002)

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